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14. ABSTRACT

The transtheoretical model (TTM) of behavior change has been used successfully to describe explain and predict clinical outcomes in patients with type 2 diabetes (T2D) exposed to various educational interventions. This study hypothesized that individuals with T2D who are in the precontemplation, contemplation, or preparation (pre-action) stages for regular self-management, exercise, smoking and carbohydrate counting and who view their own retinal images via a web portal as a part of diabetes ophthalmologic screening will progress to a higher stage of change, increase their pros of changing, decrease their cons of changing, and increase self-efficacy in managing their symptoms. Participants were recruited from the Primary Care Clinic of the Waianae Coast Comprehensive Health Center (n=125). Results showed significant differences in the transition of participants from the pre-action to action stages with regard to exercise, carbohydrate counting and smoking cessation. Participants also increased their pros of changing and decreased their cons of changing for regular exercise and carbohydrate counting.

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Introduction

Diabetes is the seventh leading cause of death in the US (Centers for Disease Control and Prevention, 2011). According to the Center for Disease Control and Prevention (CDC), *National Diabetes Fact Sheet, 2011,* an estimated 25.8 million children and adults have the disease; 7 million of who are unaware of their condition. In addition, it is estimated that 79 million adults are pre-diabetic, which is determined by blood glucose levels higher than normal (HbA1c > 5.7%). Long-term complications related to diabetes include diabetic eye disease, nerve damage (neuropathy), heart disease, stroke, kidney failure, and peripheral vascular disease, which can result in amputations and premature death. The CDC calculates health costs related to this disease to total approximately $174 billion per year.

Over the past 10 years, the rate of newly diagnosed cases has increased more than 90 percent, with more than 1.9 million new cases of diabetes diagnosed every year in adults over 20 years of age (Centers for Disease Control and Prevention, 2011). In Hawaii, there is an estimated 72,000 to 100,000 people that have diabetes, including 25,000 who remain undiagnosed, and disproportionately affecting Native Hawaiians, Asian Americans, and Pacific Islanders (Hirokawa et al., 2004). Statistics from the 2000-2002 Hawaii Behavioral Health Risk Factor Surveillance Survey indicate the following: 1) Honolulu County has the highest prevalence of type 2 diabetes in the state, at 5.8% of adults; 2) Native Hawaiians in particular have the highest prevalence of diabetes at 7.9%, followed by Filipinos at 7.5%, Japanese at 6.6% and Caucasian at 3.4%; and 3) statewide, the prevalence of retinopathy among adults with type 2 diabetes is 22%, with Native Hawaiians having the highest prevalence at 28.7% (Hirokawa et al., 2004).

Management of patients with diabetes represents an enormous cost to the military health care system (Pogach et al., 2004). The prevalence of these conditions increases with age, and is particularly high among retirees and dependents. The incidence of type 2 diabetes (T2D) in the U.S. military is higher than that of the civilian population (1.9 vs. 1.6 cases per 1,000 person years) (Paris, Bedno, Krauss, Keep, & Rubertone, 2001), even though height and weight standards are often rigorously enforced. Members of the military who become diabetic while serving on active duty face possible discharge. Although not all diabetic patients are discharged from the Army, the potential loss of personnel is troublesome. In addition, military personnel and their dependents affected by diabetes may require specialty consultation or medical interventions not available locally and may need to travel long distances for such services. This travel interrupts a service person's regular duties, removes the person from his position of military readiness, and places the burden of travel expense and medical care on military resources

Diabetic eye disease, which affects both type 1 and type 2 diabetic patients, includes diabetic retinopathy (DR), cataracts and glaucoma. The most common occurrence of the three is diabetic retinopathy, which affects 40–45% of all those diagnosed with diabetes. There are four stages of DR: mild, moderate, severe and proliferative; the latter of which, if left untreated can result in severe blurred vision or vision loss. DR is the leading cause of adult blindness in the United States (National Eye Institute National Institutes of Health, 2010a) and has been shown to be present in nearly all people diagnosed with diabetes for a duration of more than 20 years (Aiello, Cahill, & Wong, 2001). A complication of DR is diabetic macular edema (DME), which is a swelling of the retina. This can occur at any stage of DR without symptoms. DME affects approximate 10% of all diabetic patients and can be diagnosed with eye examinations; yet, left untreated, DME can result in moderate vision loss (Cavallerano, 2005).

Typically, there are no early warning signs of DR. However, eye examinations, which are the standard of care for diabetic patients, can detect the disease in its early stages. Despite that yearly eye exams are recommended for all those diagnosed with diabetes, the primary reason for vision loss due to DR is the failure to have regular eye examinations (National Eye Institute National Institutes of Health, 2010b). Studies have shown that only 50-60% of diabetic patients actually have eye exams performed (Lee, Feldman, Ostermann, Brown, & Sloan, 2003). Perceived barriers to regular eye exams include cost, misconceptions that eye exams are unnecessary, and access to care (Hartnett, Key, Loyacano, Horswell, & Desalvo, 2005).

The purpose of this project was to use the transtheoretical model (Glanz, Rimer, & Viswanath, 2008) to describe changes in behavior with a type 2 diabetic population when shown their digital retinal images and

given access to a personal health portal (PHP) website. The transtheoretical model (TTM) is one of the leading behavior change models used both in research and clinical practice (Glanz et al., 2008). The constructs and variables were developed using a comparative analysis of existing theories in behavior change (Prochaska, Diclemente, & Norcross, 1992; Prochaska, Redding, & Evers, 2008). Retinal imaging uses cameras to take high-resolution pictures of the retina. This helps detect and manage retinal disorders that can lead to vision loss or blindness. The PHP allows the patients to remotely view their retinal images and other related health educational information on their own time. The hypothesis of this study is that individuals with T2D who are in the pre-action stages of change (i.e., precontemplation, contemplation, or preparation) for regular exercise and carbohydrate counting who view their own retinal images via a web portal as a part of diabetes ophthalmologic screening will increase their pros of changing, decrease their cons of changing, and increase self-efficacy to manage their symptoms.

Body

The following are a summary of activities completed.

Task A. Comprehensive Disease Management Program (CDMP) and retinal imaging implementation – 100% complete

Estenda Solutions was contracted to both integrate CDMP with the electronic medical record (EMR) system used at Waianae Coast Comprehensive Health Center (WCCHC), and also to develop and host the PHP. Estenda Solutions is a project consulting and software development firm focused on bringing innovative healthcare initiatives from concept to reality. Since 2003 grant funded research projects included tele-ophthalmology, hepatitis, diabetes management/education, patient home monitoring, chronic kidney disease, bariatric surgery, respiratory devices, and personal health record fields. Estenda has expertise in data de-identification, aggregation, warehousing and analysis and is able to work through all aspects of a research program from pre-proposal to journal publication.

Task A.1. Configure CDMP and workflow for the proposed clinical site – 100% complete

CDMP has been integrated with NextGen, the EMR used by WCCHC. This integration provides the most efficient and accurate method of obtaining medical information and providing it to the image reader. The Nextgen – CDMP interface was developed using Estenda Solutions' standard Extract-Transform-Load (ETL) process. CDMP and EMR integrations can occur through real-time HL7 messaging or through direct database access. In this case Estenda integrated the two systems using direct database access to extract the necessary information and import it into CDMP. The extracted data elements include patient demographics, allergies, vitals, labs, medications, procedures, and diagnoses. The process is executed nightly. In order to restrict access to only study variables, reports were developed such that research personal can access the needed information without being given access to other confidential data in the EMR.

Task A.2. ***Configure CDMP as a personal health portal capable of displaying and presenting retinal images to patients via the web portal technology – 100% complete***

a. The personal health portal (PHP) website was completed and integrated in March 2011. The URL is https://prod.estenda.com/hawaii/jvn/decat. See Attachment 1 for screenshots.
b. The patent education website was completed March 2011. The URL is www.hieyes.com. See Attachment 2 for screenshots.

Task A.3. Conduct randomized control trial - 100% complete

a. ***Complete all appropriate procedures with institutional review boards – 100% complete***
Human use approvals for UH, WCCHC and the office of Research Protections, Human Research Protection Office (HRPO) were obtained. The following are dates approved.
   - University of Hawaii (UH) approved 23 February 2010
   - IRB protocols approved by Waianae Comprehensive Coast Health Center on 24 March 2010
   - Human Research Protection Office (HRPO), Office of Research Protections (ORP), US Army Medical Research and Materiel Command (USAMRMC) approved UH and WCCHC sites on 20 September 2010

   The study's human use protocols (all three) have now been closed. There were no adverse events or problems pertaining to human subjects reported throughout this study.

Task A.4. Conduct training. Train the imager and medical assistant (MA) in protocol administration. – 100% complete

A medical assistant (MA) was hired and trained in study procedures, which included participant tracking, survey administration and retinal imaging. See Attachment 3 for study protocol that was followed.

Task A.5. ***Conduct intervention and data collection. – 100% complete***

Participants were recruited from the Primary Care Clinic of the WCCHC. This center was established in 1972 to serve the needs of Oahu's rural communities on the leeward side of the island. WCCHC serves over 26,900 patients, with more than 139,200 visits annually. Located on the Waianae cost of Oahu, WCCHC's target population are native Hawaiians (51%), with a focus on chronic diseases. Other populations served include Caucasian (17%), and Asian (16%). WCCHC's patients are predominately low income, with 76% of the patients having an income level of less than 200% of Federal Poverty Level. Less than 1% of the patients are served in a language other than English (Hawaii Primary Care Association, 2010). WCCHC was selected based on the following data. The Waianae coast has a prevalence rate of diabetes of 7.1%. Native Hawaiians in particular have the highest prevalence of diabetes at 7.9%, followed by Filipinos at 7.5%, Japanese at 6.6% and Caucasian at 3.4%. Statewide, the prevalence of retinopathy among adults with T2D is 22%, with Native Hawaiians with the highest prevalence at 28.7% (Hirokawa et al., 2004).

At baseline, participants had their retinas imaged and were given a color printout of the image along with educational materials; this information was also available via the PHP. After images were remotely diagnosed, information on retinopathy diagnosis was made available to each participant via their PHP. Assessment surveys were completed at all three visits. The surveys were administered using a voiceover PowerPoint presentation in which questions were read to the subject and responses were collected via a wireless card key input. After the initial visit, follow-up survey assessments were made over the telephone if the participant could not come into the clinic.

The following instruments were used.

1. *Stage of Change for Exercise*

   This measure assesses a readiness to engage in regular exercise. Participants are asked if they engage in regular exercise, which is defined as any "planned physical activity." The staging question asks the participant to rate if they exercise regularly: yes, more than 6 months; yes, less than 6 months; no, but intend to in the next 30 days; no, but intend to in the next 6 months; and no, do not intend to in the next 6 months (Marcus, Selby, Niaura, & Rossi, 1992b; Norman, Benisovich, Nigg, & Rossi, 1998).

2. *Carbohydrate Staging*

   Constructs for these measures have been established and validated in the Stages of Intensive Therapy Questionnaire (Jones, Cleave, Tomlinson, Hamilton, & Feig, 2006). Staging for carbohydrate counting followed this sequence. After a brief description of carbohydrate counting, participants will be asked, "Do you consistently manage the amount of carbohydrate you eat each day?" Responses include the following choices: yes, more than 6 months; yes, less than 6 months; no, but intend to in the next 30 days; no, but intend to in the next 6 months; and no, do not intend to in the next 6 months.

3. *Staging for Self-Management Action Plan*

   This measure assesses if a participant has, intend to have or do not intend to have a self-management action plan to control their health condition. A self-management plan includes the following: managing triggers that can cause symptoms; regular self-testing; and monitoring symptoms and being prepared to address symptoms. There are two questions in this measure, one that asked if the participant currently has a self-management action plan and if so, a

question is asked if the plan is followed. Responses include the following choices: no, and I do not intent to in the next 6 months; no, but intend to in the next 6 months; no, but intend to in the next 30 days; and yes, I have an action plan (if yes, go to question number two). Question number two asks if the self-management plan is followed. Answers include the following: no, and I do not intend to in the next 6 months; no, but I intend to in the next 6 months; no, but I intend to in the next 30 days; yes, I have been for less than 6 months; and yes, I have been for more than 6 months. This instrument has been validated by Pro-Change Behavior Systems (Pro-Change Behavior Systems, 2010).

4. *Smoking Stage of Change*

   There are three items in this instrument. The first question asks if the participant is a current smoker. Answers include the following: yes, I currently smoke; no, I quit within the last 6 months; no I quit more than 6 months ago; and no, I have never smoked. If the participant selects that last choice, they are done with this instrument. Else, the following two questions are asked: in the last year how many times have you quit smoking for at least 24 hours; and are you seriously think of quitting smoking. The prior question will be a fill in response; the later question has the responses available: yes, within the next 30 days; yes, within the next 6 months; and no, not thinking of quitting. This instrument, which is the short form, has been validated and determined to have high reliability, internal validity, discriminative validity and predictive validity (Velicer et al., 1995; Diclemente & Prochaska, 1991).

5. *Exercise Regularly: Pros and Cons*

   This ten item measure assesses the relative importance of the advantages and disadvantages in an individual's decision to engage in regular moderate exercise**.** The psychometrics of the instrument have been established and validated at the University of Rhode Island and ProChange, Inc (Pro-Change Behavior Systems, 2010; Nigg, Rossi, Norman, & Benisovich, 1998). Responses are provided on a 5-point Likert scale from 1 = not important to 5 = extremely important. The psychometric properties demonstrate good reliability and validity. Internal consistency for the pros is α= 0.87, and α = 0.71 for the cons, with an average loading of 0.80 on the pros and 0.62 on the cons (Sarkin, Johnson, Prochaska, & Prochaska, 2001).

6. *Carbohydrate Decisional Balance*

   Ten items will be used to assess the decisional balance, pros and cons, for managing the amount of carbohydrates consumed. Responses are based on a 5-point Likert scale from 1 = not important to 5 = extremely important. Examples of the decisional balance questions are: "My blood glucose levels will improve if I control the amount of carbohydrate I eat (Pro)" and "Eating foods that are low in carbohydrates limits my food choices (Con)." This instrument has been validated by Pro-Change Behavior Systems (Pro-Change Behavior Systems, 2010).

7. *Exercise Regularly: Self-Efficacy*

   The self-efficacy short assessment instrument will be used (Benisovich, Rossi, Norman, & Nigg, 1998a; Benisovich, Rossi, Norman, & Nigg, 1998b; Marcus, Selby, Niaura, & Rossi, 1992a). For exercise, subjects will be asked to rate six items on how confident they are in exercising when other things get in the way. Responses will be recorded using a 5-point Likert scale: 1) Not confident at all; 2) Somewhat confident; 3) Moderately confident; 4) Very confident; and 5) Completely confident. Items will include references to negative affect, excuse making, exercising alone, inconvenience, resistance to others, and inclement weather. The scale has good psychometric properties (Sarkin, Johnson, Prochaska, & Prochaska, 2001): an average loading of 0.79, and an internal consistency coefficient is α= 0.88.

8. *Carbohydrate Self Efficacy*

   This assessment tool consists of 10 items that the participants will answer to rate how confident they are in managing their carbohydrate intake. Responses are recorded using a 5-point Likert scale: 1) Not confident at all; 2) Somewhat confident; 3) Moderately confident; 4) Very confident; and 5) Extremely confident. Sample items on the survey inquire about managing

carbohydrate intake during social events, holidays, when others are eating unhealthy foods, when blood glucose is low and when traveling. This instrument has been validated by Pro-Change Behavior Systems (Pro-Change Behavior Systems, 2010).

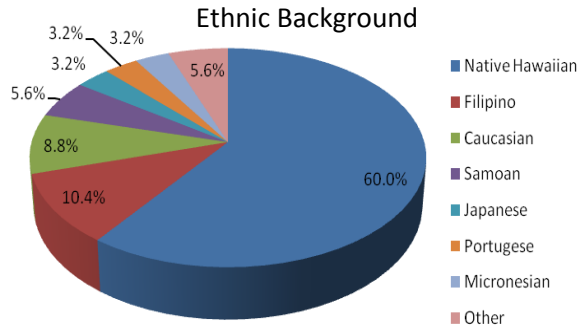
9. *Processes of Change for Exercise*

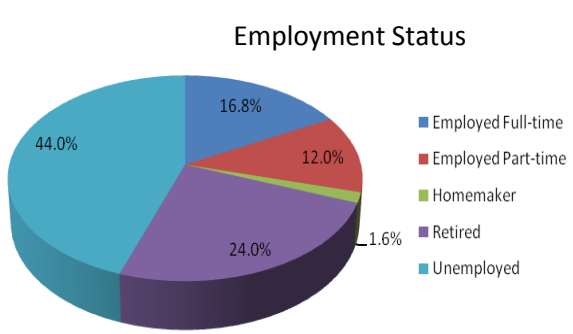
   This assessment tool consists of 28 items that rate the participants experiences regarding exercise habits. Responses are recorded using a 5-point Likert scale: 1) Never, 2) Seldom, 3) Occasionally, 4) Often, and 5) Repeatedly. There a few questions in each of the following process of change categories: consciousness raising, dramatic relief, environmental reevaluation, self reevaluation, social liberation, counter conditioning, helping relationships, self liberation, and stimulus control. This instrument has been validated by Pro-Change Behavior Systems (Pro-Change Behavior Systems, 2010; Nigg, Norman G.J., Rossi, & Benisovich, 1999).

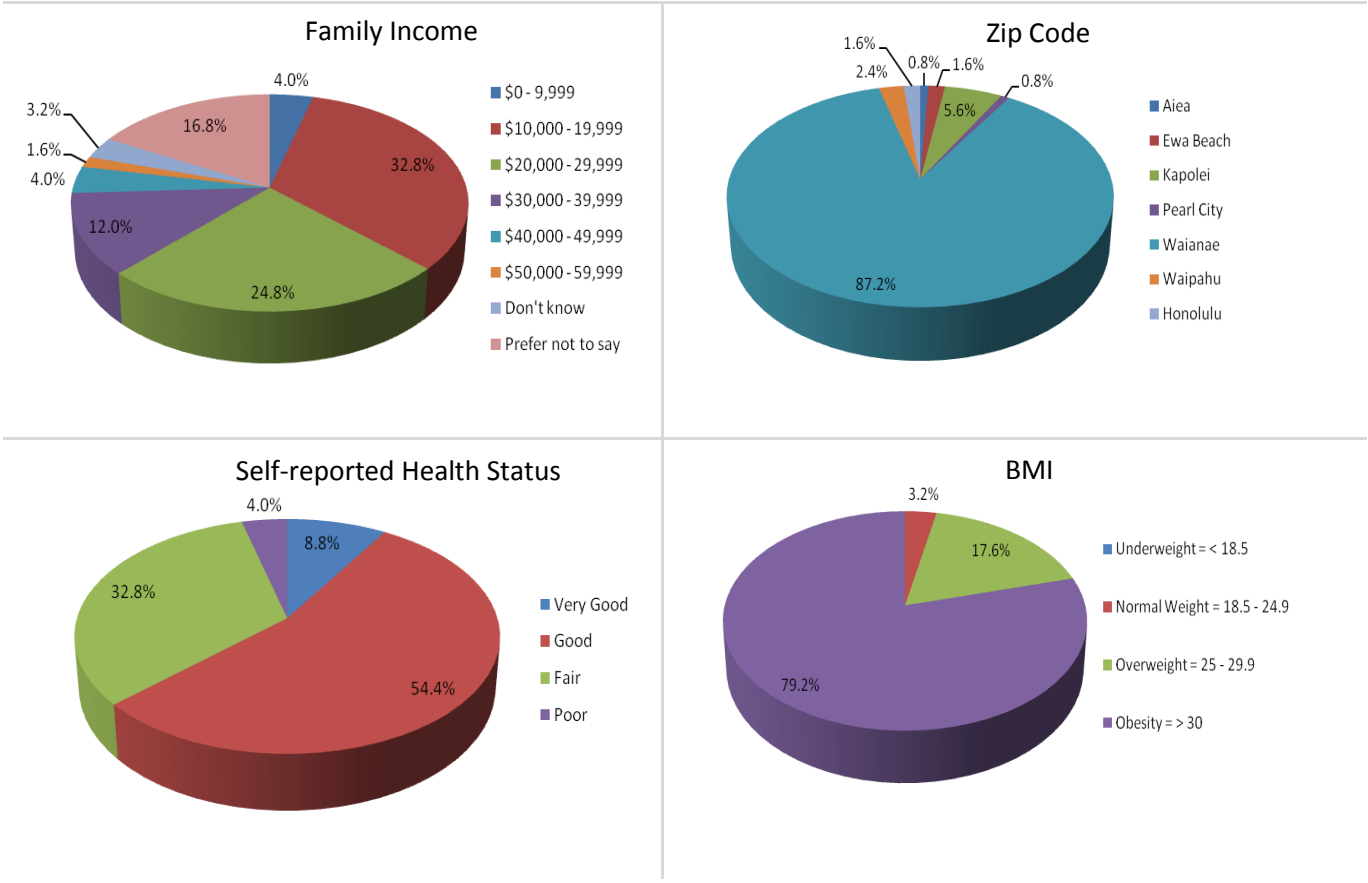
In addition, a demographics survey was used for descriptive purposes to examine trends, averages and variances in the participant population. The survey included demographic questions, such as age, gender, education, income and ethnic background. Also, in order to further investigate the mechanisms for behavior change, four informal follow-up focus group interviews were conducted to obtain some participant input. An inductive method of analysis and data collection was utilized in conducting the focus group. Open-ended questions were asked to elicit responses of "how" they feel towards retinal imaging and management of their diabetes, and why" they were or were not influenced to change behavior. A moderator helped focus the discussion; however, discussion was open to unanticipated areas that are relevant and provide insight into the mechanisms of behavior change.

A total of 160 participants were recruited and signed consent forms for this study. The retention rate was 78% with a total of 125 participants completing all three assessment visits. Assessments were administered at baseline, one and three months, and included behavioral measures of daily self-management, exercise, smoking, and carbohydrate counting. In addition to the surveys, other variables were collected from the patient's electronic medical record (if available): HbA1c, lipids, blood pressure, body mass index, and level of retinopathy. The participant demographic are as follows: n=125; mean age=53, range 27 – 77, SD=11.1; mean BMI=39.3, range 23 – 101; 50.4% female; 57% married; 16% attended "some college"; 60% Native Hawaiian, 10% Filipino, 9% Caucasian, 6% Samoan. Figure 1 shows additional demographic data on the participant population.

Figure 1. Demographic data on participant population (*n* = 125).







Task A.6. Analyze data, interpret results, and prepare report – 100% complete

For the main analysis in examining the baseline, post-intervention and three-month follow-up longitudinal data, a one-way repeated measures multivariate analysis of variance (MANOVA) (Wilk's Lambda) was conducted to compare differences between session visits. The independent variable (IV) is session (baseline, 1-month and three-month visits). The dependent variables (DVs) are stages of change (daily self-management, exercise, carbohydrate counting and smoking), self-efficacy for exercise and carbohydrate counting; decisional balance (pros and cons) for exercise and carbohydrate counting. The purpose of this test is to examine session differences between the multiple DVs. The MANOVA multivariate method is used because it accounts for the effects of other variables in calculating differences, thus reducing Type 1 error. Post-hoc chi-squared analyses are conducted for the categorical variables of stage of change and analysis of variance tests are conducted for the continuous variables of self-efficacy and decisional balances are conducted for follow-up comparisons.

The MANOVA analysis showed significant multivariate effect, Wilk's $\lambda = .433$, $F = 12.419$, $p < .0005$, partial $\eta^2 = .342$, indicating a difference between session visits. Chi-square tests showed that there were significant differences between the three session visits for all stage of change measures: daily self-management, $\chi^2(4, N = 375) = 149.767$, $p < .0005$; exercise, $\chi^2(2, N = 375) = 41.177$, $p < .0005$; carbohydrate counting, $\chi^2(2, N = 375) = 29.978$, $p < .0005$; and smoking, $\chi^2(4, N = 375) = 9.900$, $p < .05$. Significant ANOVA effects were found for exercise pros, $F(2, 372) = 5.567$, $p < .004$, exercise cons, $F(2, 372) = 9.844$, $p < .0005$, carbohydrate counting pros, $F(2, 372) = 11.166$, $p < .0005$, and carbohydrate counting cons $F(2, 372) = 8.555$, $p < .0005$. There were no significant effects for exercise self-efficacy, carbohydrate counting self-efficacy and exercise process of change. Table 1 shows the means, standard deviations, and results of Sheffe post-hoc contracts across the three session visits.

Table 1. Means and Post-hoc for Pros and Cons and Self Efficacy by Visit Number

	Visit 1	*Visit 2*	*Visit 3*	*N*	*Scheffe Post hoc**
Exercise Pros *	12.15 (4.01)	13.26 (4.374)	13.98 (4.66)	125	Visit 1 ↔ Visit 3
Exercise Cons *	10.92 (4.67)	9.18 (4.25)	8.70 (3.52)	125	Visit 1 ↔ Visit 2 Visit 1 ↔ Visit 3
Exercise Self Efficacy	16.90 (5.82)	16.77 (6.82)	16.41 (8.07)	125	
Carb Counting Pros *	15.53 (5.27)	17.46 (5.58)	18.78 (5.54)	125	Visit 1 ↔ Visit 2 Visit 1 ↔ Visit 3
Carb Counting Cons *	12.89 (4.74)	12.58 (5.57)	15.30 (6.65)	125	Visit 1 ↔ Visit 3 Visit 2 ↔ Visit 3
Carb Counting Self Efficacy	27.58 (10.07)	30.01 (10.10)	28.75 (11.69)	125	

* $p < .05$. Standard Deviations appear in parentheses below means.

Specific to the hypothesis we separated those subjects that were in the pre-action stages of change (i.e., precontemplation, contemplation, or preparation) for each of the related behaviors. We then examined DVs of decisional balance and self-efficacy as it related to these pre-action subjects with the IV of session visit. See Table 2 below for means and standard deviations for decisional balance and self efficacy. An analysis of variance showed that the effects for exercise pros, $F(2, 306) = 9.850$, $p < .0005$, exercise cons, $F(2, 306) = 10.269$, $p < .0005$, carbohydrate counting pros, $F(2, 300) = 10.264$, $p < .0005$, and carbohydrate counting cons $F(2, 300) = 8.418$, $p < .0005$ were significantly different across all three visits, however, the effects were not significantly different for self-efficacy for either exercise and carbohydrate counting behaviors.

Table 2. Means and Post-hoc for Pros and Cons and Self Efficacy by Visit Number for those in pre-action stages of change

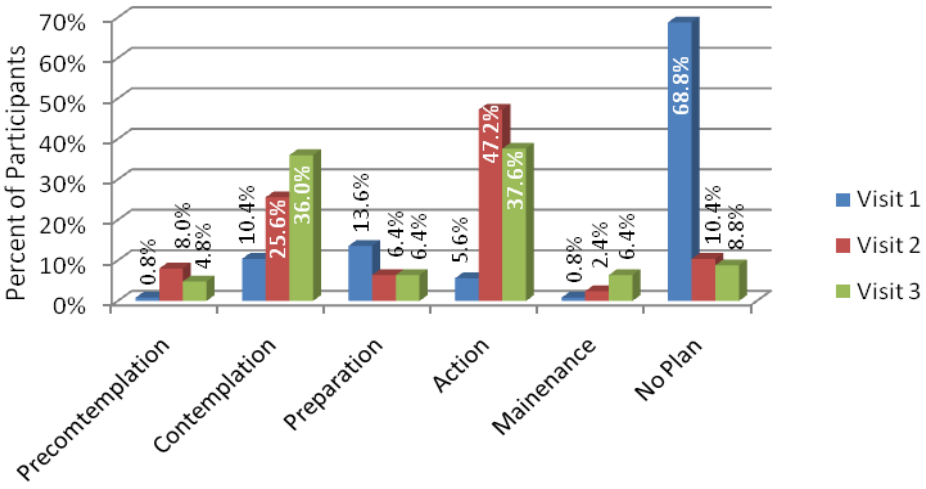
	Visit 1	*Visit 2*	*Visit 3*	*N*	*Scheffe Post hoc**
Exercise Pros *	11.41 (3.79)	13.15 (4.46)	14.00 (4.52)	103	Visit 1 ↔ Visit 3
Exercise Cons *	11.07 (4.58)	9.03 (4.12)	8.67 (3.52)	103	Visit 1 ↔ Visit 2 Visit 1 ↔ Visit 3
Exercise Self Efficacy	16.27 (5.53)	16.71 (6.80)	15.9 (8.02)	103	
Carb Counting Pros *	14.87 (5.32)	17.04 (5.62)	18.36 (5.62)	101	Visit 1 ↔ Visit 2 Visit 1 ↔ Visit 3
Carb Counting Cons *	12.64 (4.74)	12.76 (5.54)	15.60 (6.93)	101	Visit 1 ↔ Visit 3 Visit 2 ↔ Visit 3
Carb Counting Self Efficacy	26.64 (10.48)	29.65 (10.17)	27.84 (12.21)	101	

* $p < .0005$. Standard Deviations appear in parentheses below means.

Stage Distributions

Figures 2-5 below are the stage distributions for the participants that completed all three visits (n = 125). For this study we examined daily self-management, exercise, carbohydrate counting and smoking cessation. Figure 2, which shows the distribution for daily self-management, 24.8% of the subject population was in the pre-action, or risk stages of precontemplation, contemplation and preparation, at visit one. By visit three, there was actually an increase in number of participants reporting to be in the pre-action stages, at 47%. This may be explained by the large amount of those, 68.8%, that started with no plan at visit one, and having developed a self-management plan by visit three (8.8% had no plan at visit three). Hence those with no self-management plan at visit one, may have moved to the pre-action stages of having a daily self-management plan, but not yet ready for action.

Figure 2. Means for daily self-management stage of change across three visits (n = 125)



For regular exercise behavior at visit one, 82.4% of participants were in the pre-action stages (see Figure 3). By visit three, 46.4% reported still being in the pre-action stages for regular exercise. This is indicates that 36% of participants progressed from pre-action into the action stages.

Figure 3. Means for exercise stage of change across three visits (n = 125)

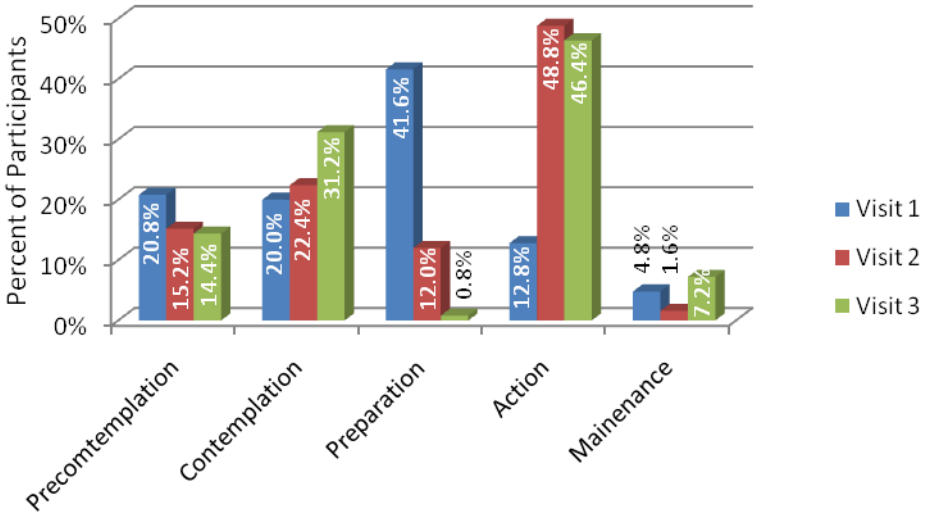
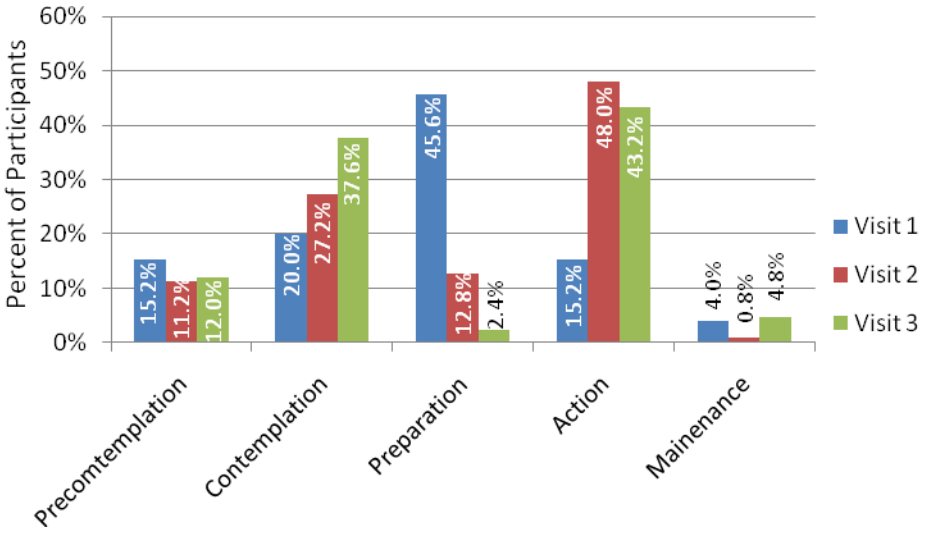


Figure 4 shows the stage distribution for carbohydrate counting. For this behavior, 80.8% of the participants reported being in the pre-action stages at visit one. At visit three 52% reported being in the pre-action stages. This indicates that 28.8% of the participants moved from pre-action to action.

Figure 4. Means for carbohydrate counting stage of change across three Visits (n = 125)



For smoking cessation, 91.2% of participants at visit one were in the pre-action stages. At visit three, 83.2% of participants reported being in the pre-action stages. This indicates that 8% of participants moved from pre-action to action stages of change for smoking cessation.

Figure 5. Means for smoking cessation stage of change across three visits (n = 125)

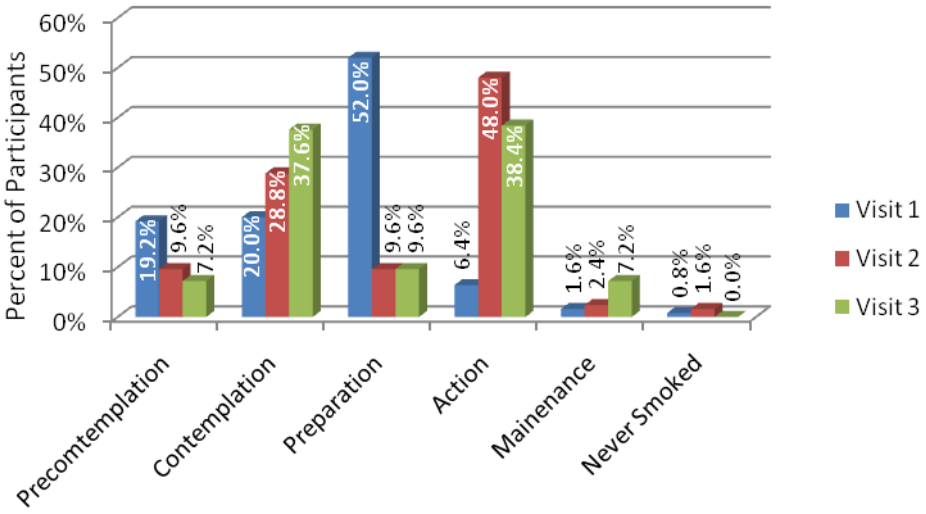
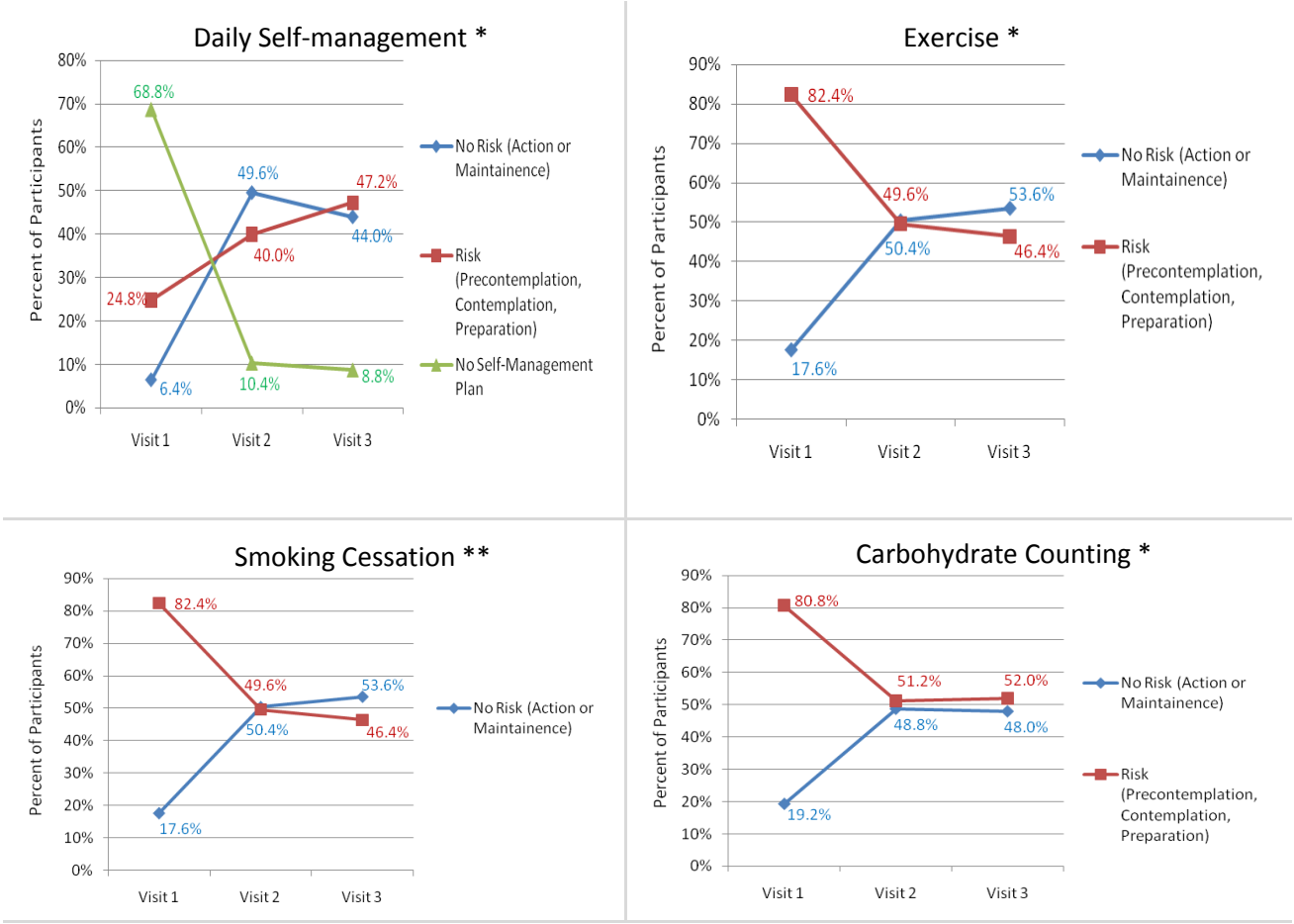


Figure 6 below graphs the progression from visit one to visit three for all four of the stage of change behaviors. For exercise, carbohydrate counting and smoking cessation, there is an inverse relationship in population percentage of those transitioning to no risk or action stages of change from the risk or pre-action

stages across the three visits. Looking at daily self management, you can see a big decrease in those with no plan that may explain the increase with those in the pre-action stages.

Figure 6. Stage of change transition from pre-action or at risk (pre-contemplation, contemplation and preparation stages) to action or no risk (action or maintenance) for daily self-management (n=125), exercise (n=125), smoking cessation (n=125) and carbohydrate counting (n=125).



* p < .0005, ** p < .05.

Processes of Change for Exercise

The processes of change are activities that people engage in order to progress through the stages of change. There were 10 basic process of change that were identified and validated as highly reliable measures (Prochaska, Velicer, Diclemente, & Fava, 1988). These include the following: 1) consciousness raising, which is awareness about causes and consequences about behaviors; 2) dramatic relief, initial increase in emotions followed by a decrease if action is taken; 3) self-reevaluation, one's cognitive and affective self-assessment on an unhealthy behavior; 4) environmental reevaluation, how one's behavior affects the social environment; 5) self-liberation, the belief that one can change; 6) social liberation, and increase in social opportunities for those that are deprived; 7) counterconditioning, which is positive substitute behaviors; 8) stimulus control, removing negative cues and incorporating healthy one; 9) contingency management, consequences in either healthy or unhealthy behavior; and 10) helping relationships, which is positive support for healthy behavior change (Prochaska & Velicer, 1997; Prochaska et al., 2008).

The results for processes of change for regular exercise are shown in Figure 7 below. Despite that there is no mathematical relationship between the stages of change and processes of change, there have been

systematic relationships discovered. The relationships suggest that in the earlier stages of change people apply conscious raising, dramatic relief self-reevaluation and environmental reevaluation (Glanz et al., 2008). As people progress to the action and maintenance stages, people apply self-liberation, helping relationships, counterconditioning, stimulus control and social liberation processes. An analysis of variance demonstrates that the effects for environmental reevaluation, $F(2,371) = 5.632$, $p < .005$, helping relationships, $F(2, 3367) = 4.469$, $p < .05$, and social liberation, $F(2, 371) = 5.448$, $p < .05$ were significantly different across the three visits. Interestingly, these processes all were related to social components; environmental reevaluation looking at impact of behavior on the social environment; helping relationships seek and use social support; and social liberation, which relates to social norms. Table 3 lists the mean scores for all of the processes measured for exercise. Table 3 lists the mean scores for all the processes of change across the three visits.

Figure 7. Mean Scores for Processes of Change for Exercise Across Three Visits.

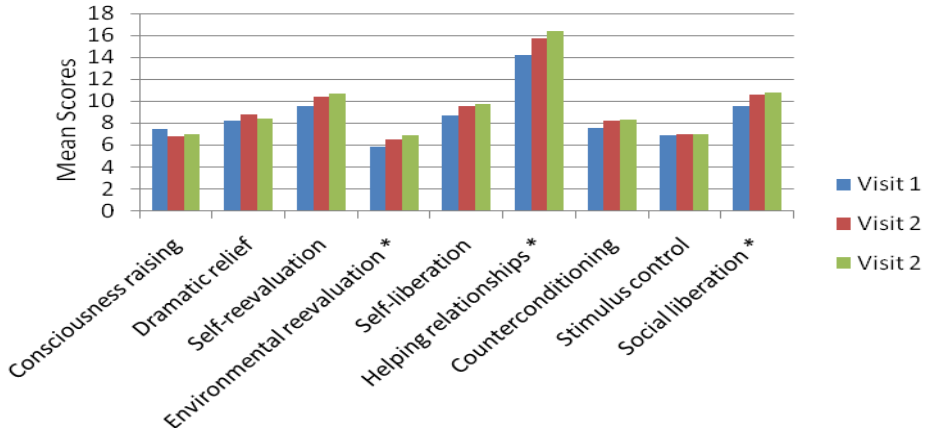


Table 3. Means, Standard Deviations and Post-hoc for Exercise Processes of Change

	Visit 1	*Visit 2*	*Visit 3*	*N*	*Scheffe Post hoc**
Consciousness raising	7.44 (2.95)	6.82 (3.36)	6.95 (3.88)	125	
Dramatic relief	8.21 (2.83)	8.78 (3.09)	8.38 (3.31)	125	
Self-reevluation	9.56 (3.62)	10.42 (3.83)	10.70 (4.26)	125	
Environmental reevaluation *	5.85 (2.29)	6.55 (2.46)	6.86 (2.54)	125	Visit 1 ↔ Visit 3
Self-liberation	8.68 (3.34)	9.56 (4.08)	9.70 (4.26)	124	
Helping relationships *	14.18 (4.82)	15.73 (6.03)	16.36 (6.71)	123	Visit 1 ↔ Visit 3
Counterconditioning	7.60 (3.01)	8.24 (3.58)	8.27 (4.20)	125	
Stimulus control	6.88 (3.42)	7.70 (3.97)	6.94 (3.65)	124	
Social liberation *	9.54 (3.48)	10.60 (3.00)	10.80 (3.28)	125	Visit 1 ↔ Visit 2 Visit 1 ↔ Visit 3

* $p < .0005$. Standard Deviations appear in parentheses below means.

Clinical Measures

In examining the clinical measures from patient medical records, we were able to obtain 111 of the participant's laboratory data for HbA1c. Only 53 of those patients had a post-intervention HbA1c lab available. A paired-sample t-test was conducted to compare the baseline HbA1c to the post-intervention HbA1c values. Although the HbA1c values decreased, there was no significant difference between the baseline HbA1c (M = 8.417, SD = 2.119) and the post-intervention HbA1c (M=8.215, SD=2.24), $t(52)=1.076$, $p > .05$. A one-way between subjects analysis of variance was conducted to compare the effect of HbA1c pre- and post-intervention with all four of the stage of change variables (daily self-management, exercise, carbohydrate counting and smoking cessation) categorized as pre-action and action stages at visit number 3. There was no significant effect of HbA1c on daily self-management, exercise, or carbohydrate counting. The results did show a significant effect on smoking risk and HbA1c, $F(2, 108) = 4.438$, $p < .05$. A post hoc analysis Tukey HSD test showed the mean HbA1c for those that were in the pre-action stage of quitting smoking (M = 8.066, SD 2.008) was significantly different than those that reported never have smoked (M = 9.209, SD 2.744) at $p < .05$ level of significance.

Results of the non-mydriatic retinal imaging (n = 125) diagnosed 16 people with nonproliferative retinopathy and 15 people were diagnosed with proliferative retinopathy. All of the diagnoses of retinopathy were in the left eye. An average of 6.5% of the images were ungradable. This could be due to factors, such as, age, presence of central cataract, pupil diameter, or iris color. None of the patients were diagnosed with macular edema. A chi-square test of independence was performed to examine the relation between retinopathy diagnosis and stage of change for daily self-management, exercise, carbohydrate counting and smoking. There were no significant relations between these variables.

Analysis of lipids was not conducted due to the lack of data. Less than 5% of participants had lipid panel laboratory results for either baseline or post-intervention.

Key Research Accomplishments

Task A. Comprehensive Disease Management Program (CDMP) and retinal imaging implementation

Task A.1. Configure CDMP and workflow for the proposed clinical site

a. CDMP has been configured and integrated with WCCHC NextGen electronic health record.

Task A.2. Configure CDMP as a personal health portal capable of displaying and presenting retinal images to patients via the web portal technology

a. Patient portal completed.
b. Educational website completed.

Task B. Conduct randomized control trial

Task B.1. Complete all appropriate procedures with institutional review boards

a. Human use approvals for UH, WCCHC and the office of Research Protections, Human Research Protection Office (HRPO) were obtained and currently closed-out on completion of the study.

Task B.2. Conduct training. Train the imager and medical assistant (MA) in protocol administration.

a. Imager and medical assistant were trained on study procedures.

Task B.3. Conduct intervention and data collection.

a. Intervention was conducted, 125 participants completed all three visits.
b. Data was collected, including clinical measures from CDMP.

Task B.4. Analyze data, interpret results, and prepare report

a. Data has been analyzed, results interpreted and reported above.
b. Abstract has been submitted to the Advancing Native Health and Wellness Conference, July 31 – August 5, 2012 in Anchorage, Alaska. Acceptance is still pending.

Conclusions

For this study, the transtheoretical model was chosen to examine behavior change when patients diagnosed with type 2 diabetes are shown their retinal images and related eye disease information. The TTM is one of the most widely used models of health behavior and is easily applied to many areas in health behavior. The TTM was designed to be generalizable across a wide variety of populations and behaviors (Prochaska et al., 1994). TTM also used intuitive logic in assessing the constructs, utilizing the stage of health behavior change as the main construct, versus cognitive variables, such as, perceived risk or barriers, in which the other earlier theories revolved. The focus of the TTM is on individual change, versus interpersonal or community models. Despite that there may be other theories that are applicable to this study's purpose, the TTM was chosen due to the wide use in diabetes and individual behavior focus.

A recent literature search was conducted using Academic Search Premier, Medline, and Psychology and Behavioral Science collection databases. Key search terms were telemedicine, diabetes, health behavior theory, retinal imaging, retinopathy, teleretinal imaging, diabetes education, and Internet for studies dated from 1997 through 2012. No published articles were found that examined the impacts of digital retinal imaging and diabetes education, looking at behavior and health outcome effects. Thus from our knowledge, this is the first study to look at a digital retinal imaging intervention for diabetes health outcomes. There is one retrospective study that looked at patient clinical outcomes and teleretinal imaging. This was a retrospective study done at the Joslin Diabetes Center (Harvard Medical School) (n = 13,752). Results demonstrated a relationship between patients that received teleretinal imaging and improved HbA1c, LDL and systolic blood pressure over time (2 year span), as well as improved adherence to subsequent eye care (Fonda et al., 2007).

Using the TTM model, results showed significant differences in the transition of diabetic patients from the pre-action to action stages with regard to exercise, carbohydrate counting and smoking cessation. There were also significant differences between he visits for daily self-management; although the percentage of those in the risk category increased over time, there was a drastic decrease in those that reported having no daily self-management plan across the three visits. Specific to the hypothesis, individuals with T2D who are in the pre-action stages of change for regular exercise and carbohydrate counting who were given access to their own retinal images via a web portal as a part of diabetes ophthalmologic screening increased their pros of changing and decreased their cons of changing. We did not demonstrate a statistically significant difference in self-efficacy related to regular exercise or carbohydrate counting. This may be due to the nature of the intervention, which is educational and not therapeutic, or possibly due to the time frame of the study of only nine months.

Although the web logs show that very few of the participants actually logged into the PHP after they were imaged, all participants were given a printed copy of both their retinal images and the educational website. Because of this, we believe that there may be an assessment effect from the survey instruments and administration of the surveys. Based on the results from the processes of change, this population group is sensitive to social components related to behavior change. Specifically, there were significant differences between visits in helping relationships (seeking and using social support), social liberation (realizing that social norms are changed to support health behavior), and environmental reevaluation (the impact of their behavior on one's social or physical environment). In the follow-up focus group sessions, we found that a major theme in the desire to change is the impact on family, both in not being a burden and being a good role model to children. All participants reported enjoying talking and learning in the group setting about how to take better care of their diabetes. Regarding the technology, the participants liked the non-mydriatic digital retinal imaging and remote diagnosis without having to travel to another health care facility. This may indicate that despite that most did not log into the PHP; the whole process of the study affected the patients positively.

Of significance to the military may be a contribution to the understanding of how to treat chronic disease. The cost of treating the long-term complications of diabetes consumes a major part of the Veterans Administration

medical budget and is an important component of the Department of Defense expenditures. The Veterans Health Administration identifies diabetes as a substantial burden. This study can contribute to a better understanding of methods that be more appropriately suit the needs of the patients. Future studies are needed to better understand the affects of technology, education and retinal imaging related to behavior change and diabetes management.

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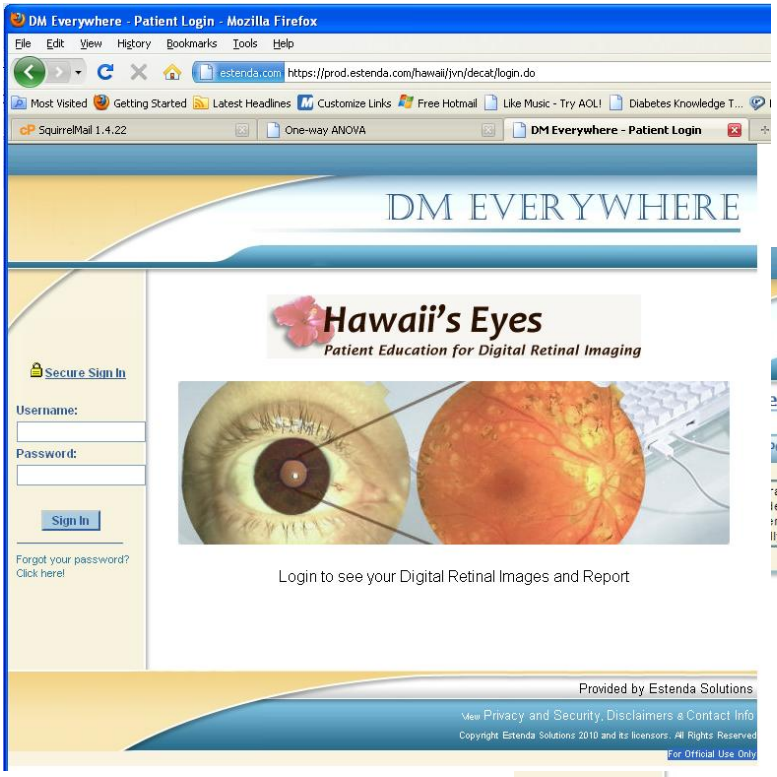
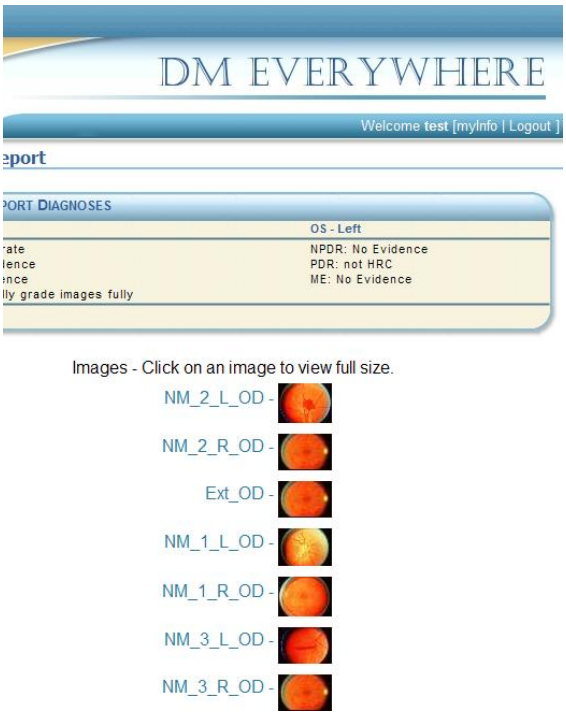
Acronyms

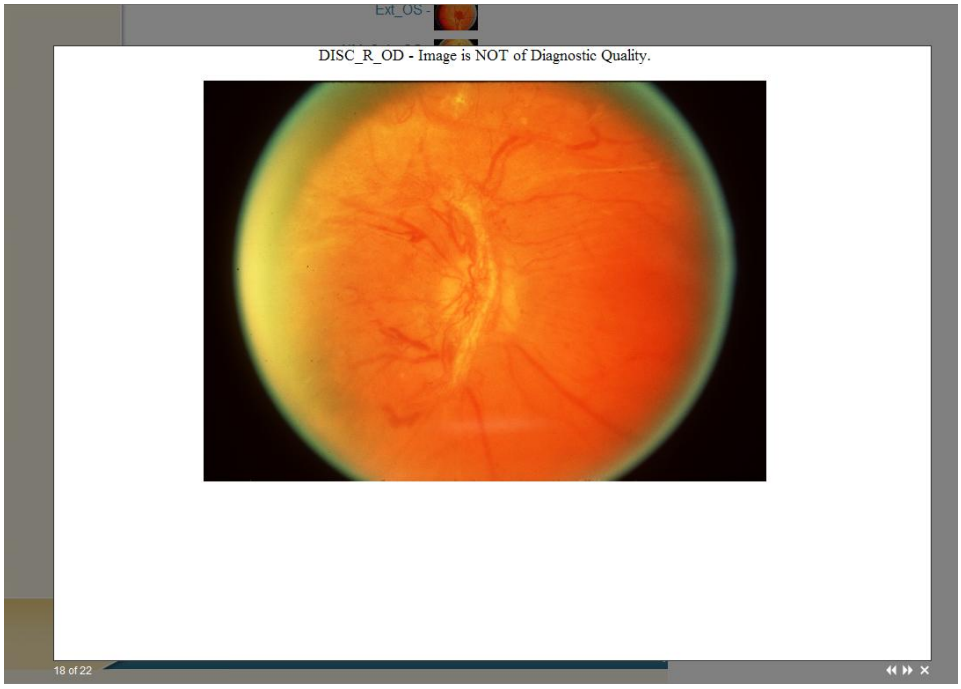
CDC	--	Center for Disease Control and Prevention
CDMP	--	Comprehensive Disease Management Program
DME	--	Diabetic macular edema
DR	--	Diabetic retinopathy
DV	--	Dependent Variable
HbA1c	--	Hemoglobin A1c
HRPO	--	Human Research Protection Office
IV	--	Independent Variable
MA	--	Medical assistant
NCE	--	No cost extension
PHP	--	Personal health portal
TTM	--	Transtheoretical model
T2D	--	Type 2 diabetes
URL	--	Uniform resource locator
UH	--	University of Hawaii
WCCHC	--	Waianae Coast Comprehensive Health Center

Attachment 1
Patient Portal

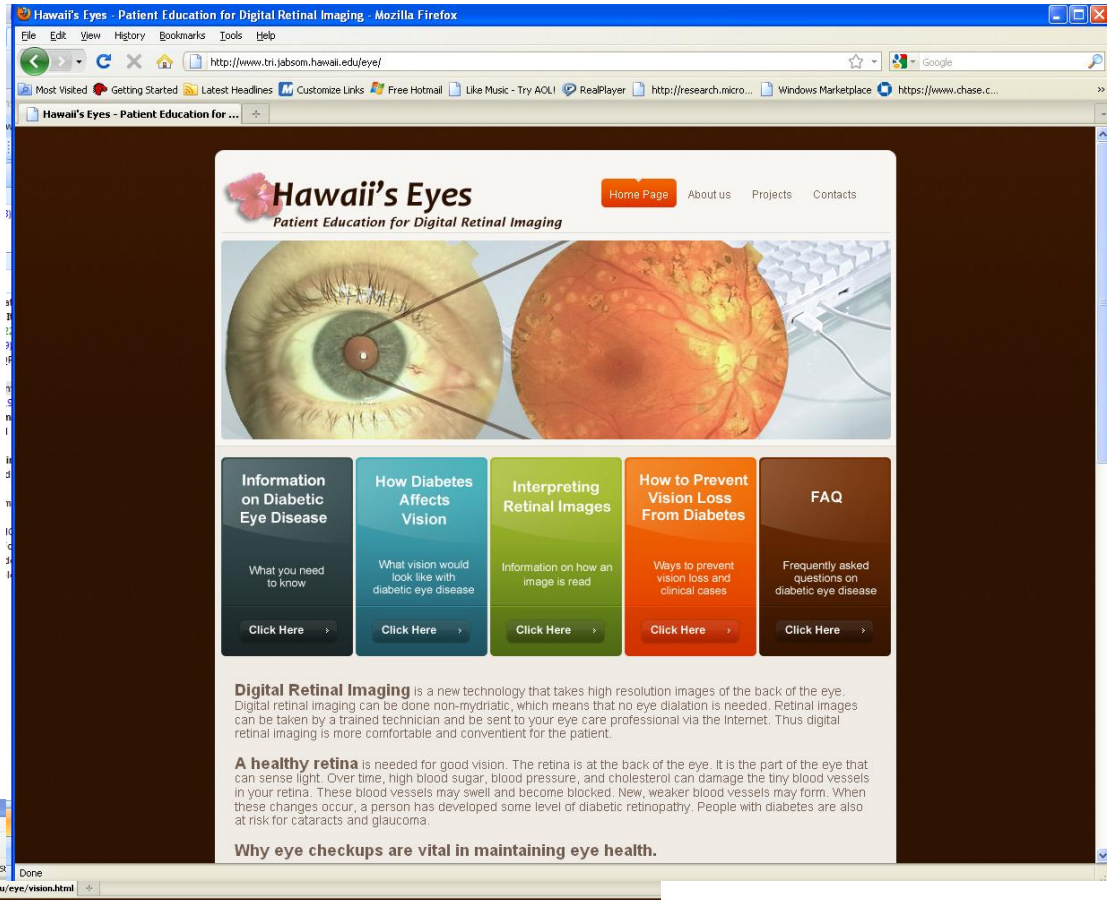


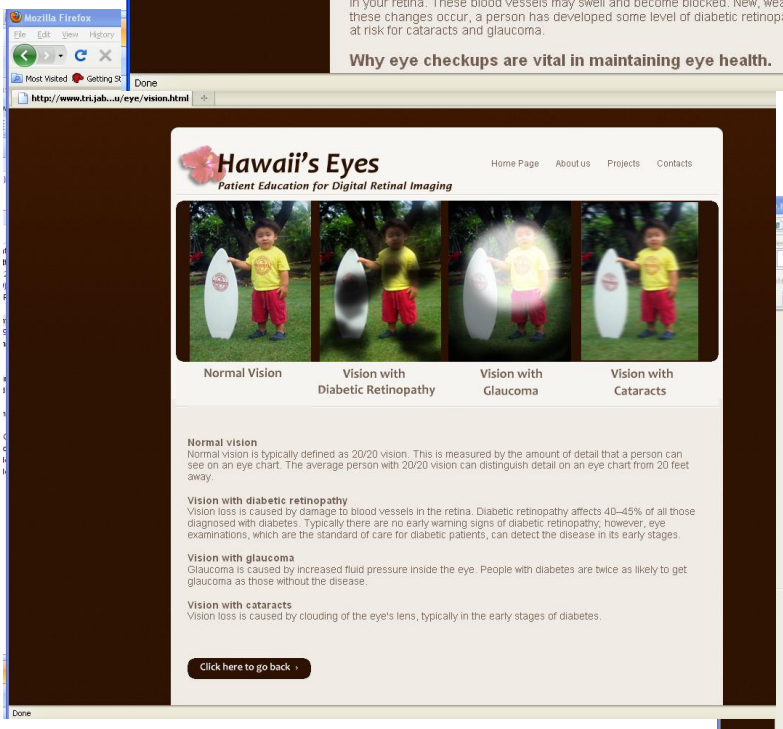
Patients are able to login into the PHP and see their personalized image diagnosis reports and click on images for larger view.

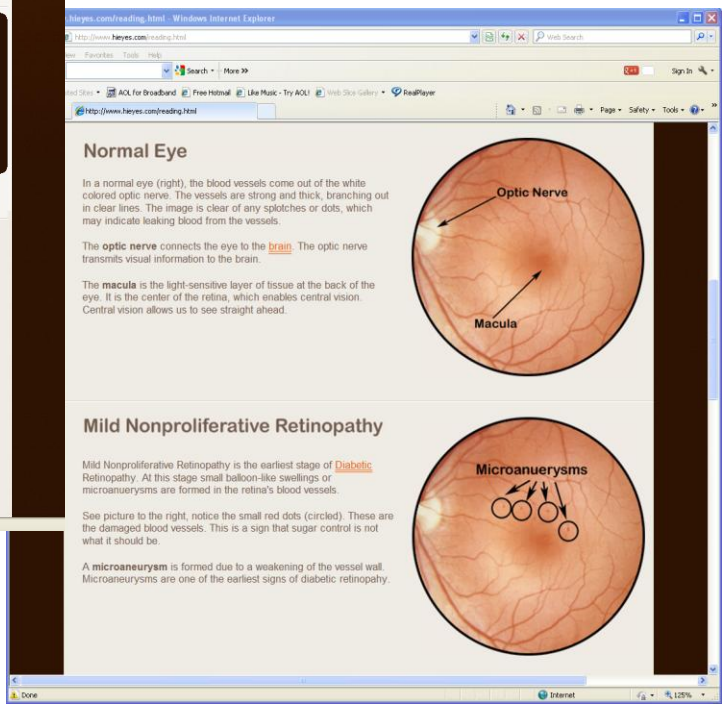




Attachment 2
Educational Website







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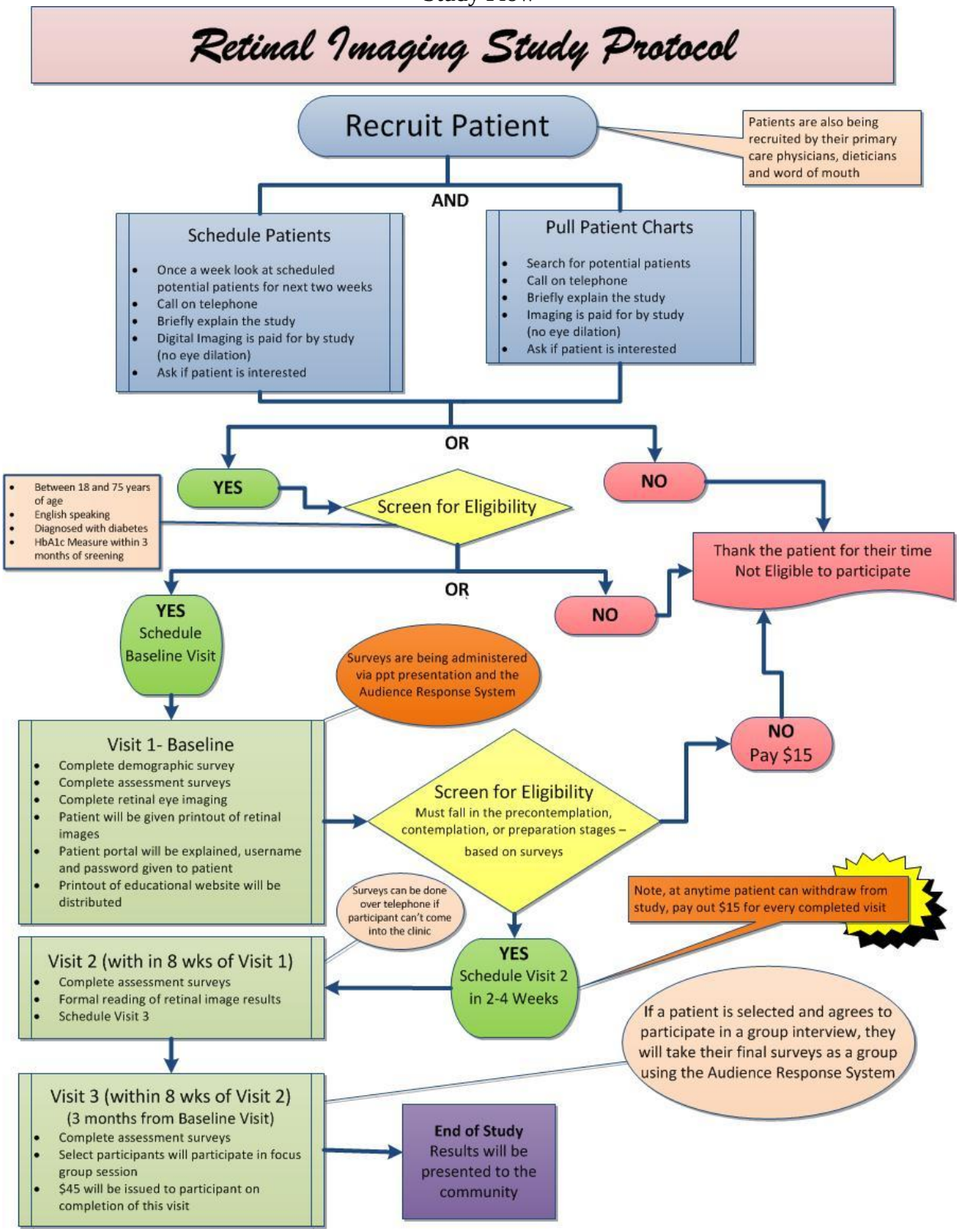
Study Flow